K063228

DEC - 8 2006

Date: October 24, 2006

510(k) Summary

1. 510(k) owner (submitter)

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in U.S.	Koji Nishida KURARAY AMERICA, INC. 600 Lexington Avenue, 26th Floor New York, NY 10022 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

2. Name of Device

1) Trade / Proprietary name	SURFACE COAT
2) Classification name	Coating, Filling Material, Resin (21 CFR section 872.3310. Product code: EBD)
3) Common name	Resin glaze material

3. Predicate device

1) BISCOVER LIQUID POLISH	510(k) Number:	K030354
	Product Code:	EBD
	21 CFR Section:	872.3310
	Applicant:	BISCO, INC.
2) BISCOVER LV	510(k) Number:	K043168
	Product Code:	EBD
	21 CFR Section:	872.3310
	Applicant:	BISCO, INC.
3) C&B METABOND	510(k) Number:	K960464
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	PARKELL, INC.
4) CHROMA ZONE COLOR STAIN	510(k) Number:	K012737
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	KURARAY MEDICAL, INC.
5) PANAVIA F 2.0	510(k) Number:	K032455
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	KURARAY MEDICAL, INC.

4. Description of device

SURFACE COAT is a single-component, light-cure resin glaze material that provides a clear and smooth surface, consisting of a multi-functional acrylate monomer that provides excellent durability and may reduce or even eliminate the need for manual polishing. SURFACE COAT has virtually no surface oxygen inhibition layer.

5. Intended use

SURFACE COAT, the applicant device, is used to glaze/polish following restorations:

- Direct and indirect composite resins
- Acrylic provisional crowns and bridges
- Acrylic appliances
- Glass ionomers and resin-modified glass ionomers

SURFACE COAT shares the same intended use as those included in the intended uses of BISCOVER LIQUID POLISH and BISCOVER LV, the predicate devices. SURFACE COAT is indicated for more limited uses than the predicate devices, as it is not used for enamel.

6. Substantial equivalence

The safety and effectiveness of SURFACE COAT, the applicant device, are equivalent to the predicate devices.

1) Effectiveness / Performance

Since there is no applicable FDA's recognized standard or international standard concerning performance of this type of device, certain specifications are designed for SURFACE COAT, the applicant device, and tested accordingly in comparison with the predicate devices validating that the applicant device is substantially equivalent to the predicate devices in terms of the effectiveness and performance.

2) Safety

SURFACE COAT, the applicant device, contains chemical ingredients which have been used in the predicate devices and copes with any possible risk in a similar manner as the predicate devices suggesting the safety of the applicant device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2006

Kuraray Medical, Incorporated
C/O Mr. Koji Nishida
Kuraray America, Incorporated
600 Lexington Avenue, 26th Floor
New York, New York 10022

Re: K063228
Trade/Device Name: Surface Coat
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: October 24, 2006
Received: October 31, 2006

Dear Mr. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

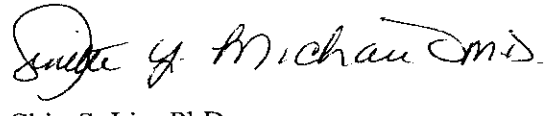
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063228

Device Name: SURFACE COAT

Indications for Use:

SURFACE COAT is used to glaze/polish following restorations:
- Direct and indirect composite resins
- Acrylic provisional crowns and bridges
- Acrylic appliances
- Glass ionomers and resin-modified glass ionomers

Prescription Use x AND/OR Over-The-Counter Use N/A

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) K063228